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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/798,465	03/11/2004	Michael D. Laufer	LAUFNZ00200	6106
40518	7590	01/29/2009		
LEVINE BAGADE HAN LLP			EXAMINER	
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/798,465	<b>Applicant(s)</b> LAUFER ET AL.	
	<b>Examiner</b> JING OU	<b>Art Unit</b> 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 24 November 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-8, 10, 14-29 and 32-38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10, 14-29 and 32-38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date: _____   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. This action is responsive to the amendment along with RCE filed on November 24, 2008. Claims 1-8, 10, 14-29, and 32-38 are pending. Claim 38 is newly added. Claims 1, 28, and 38 are independent.

#### ***Continued Examination Under 37 CFR 1.114***

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/23/2007 has been entered.

#### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-8, 10, 14-29, and 32-38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The recitations "a number of protrusions on each anchor are aligned along an axis of the first and second anchor member" in Claim 1, "a number of protrusions on each anchor means are

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aligned along a respective axis of the anchor means" in Claim 28, and "the first and second anchor members include a number of uniformly spaced protrusions located on a respective surface of the first or second anchor member" in Claim 38 do not have sufficient support in the original disclosure and are considered as new matter.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 28, 29, and 32-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 28, the word "means" is preceded by the word(s) "first," "second," and "anchor" in an attempt to use a "means" clause to recite a claim element as a means for performing a specified function. However, since no function is specified by the word(s) preceding "means," it is impossible to determine the equivalents of the element, as required by 35 U.S.C. 112, sixth paragraph. See *Ex parte Klumb*, 159 USPQ 694 (Bd. App. 1967).

### ***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1-8,10,14-18,20-29,32,33,35, and 38 are rejected under 35 U.S.C. 102(e) as being anticipated by Ryan, et al. (US Pub. No.: 2003/0191495 A1) in view of either Kamiya et al (US Pat. No.: 5,192,301) or Mitchell et al (US Pub. No.: 2003/0040746).

Ryan discloses a surgical fastener having two end anchor portions and a central connecting portion. The anchors are formed of a polymeric material, and the connector portion is formed of a polymer material more elastic than the anchors. The materials are bioabsorbable and induce tissue ingrowth. The device is expandable due to the material, compression or inflation. The device can include glue or drugs. As disclosed in

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paragraph 42, the tissue anchors can incorporate a roughened tissue-contacting surface, thus they include the claimed “protrusions”. See paragraphs 6,8,42-44,48,52-55,64 and 73.

Ryan does not appear to disclose that the protrusions are aligned uniformly along an axis of the first or second member.

However, Kamiya et al teaches a surgical device comprising protrusions (226, 237, or 258) aligned uniformly along an axis on the surface of the device (Figs. 22, 23, and 25). Alternatively Mitchell et al teaches a surgical device comprising protrusions (92) aligned uniformly along an axis on the surface of the device (Fig. 5).

It would have been obvious at the time of the invention was made to modify the device of Ryan to include protrusions aligned uniformly along an axis on the surface of the device as taught by either Kamiya et al or Mitchell et al. The suggestion/motivation for doing so would have been to provide a rough surface for effective fixation of the device to the body (Kamiya et al, Col. 7, lines 8-21 or Mitchell et al, Para.[0071]).

10. Claims 19,34,36 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ryan, et al. (US Pub. No.: 2003/0191495 A1) in view of either Kamiya et al (US Pat. No.: 5,192,301) or Mitchell et al (US Pub. No.: 2003/0040746), as applied to claims 1 and 28 above, and further in view of Ory, et al. (US Pat. No.: 6692506) or Thill, et al. (US Pub. No.: 2003/0028213 A1) and Beer, et al. (US Pat. No.: 2003/0139819).

Ryan in view of either Kamiya et al or Mitchell et al discloses the invention as claimed with the exception of the specific anchor materials. Both Ory and Thill disclose

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at least one of the claimed anchor materials in similar devices. It would have been obvious to have used a bioabsorbable material taught by either Ory or Thill for the anchors of Ryan in view of either Kamiya et al or Mitchell et al, as these materials are bioabsorbable, induce tissue ingrowth or attach well to tissue. Ryan in view of either Kamiya et al or Mitchell et al also fails to specify that the protrusions include a bioactive substance. However, Beer discloses a septal occluder body made out of a bioabsorbable material with a drug therein. It would have been obvious to have made the anchor portions, including the protrusions, out of a bioabsorbable material with drugs in order to treat a condition or prevent infection or induce growth into the occluder.

### ***Response to Arguments***

11. Applicant's arguments with respect to claims 1-8, 10, 14-29, and 32-38 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JING OU whose telephone number is (571)270-5036. The examiner can normally be reached on M-F 7:30am - 5:00pm, Alternative Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Uyen (Jackie) T Ho can be reached on (571)272-4696. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JO

/(Jackie) Tan-Uyen T. Ho/  
Supervisory Patent Examiner, Art Unit 3773